

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING	)	
PHARMACY, INC. PRODUCTS LIABILITY	)	
LITIGATION	)	
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THIS DOCUMENT RELATES TO:	)	MDL No. 2419
	)	Dkt. No 1:13-md-2419 (RWZ)
ALL CASES	)	
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**SAINT THOMAS ENTITIES' RESPONSE TO PSC'S MEMORANDUM IN SUPPORT  
OF ITS PROPOSAL FOR INITIAL TRIAL SETTING AND PRETRIAL DEADLINES  
AND CROSS-MOTION TO AMEND CASE MDL ORDER NO. 9**

In accordance with MDL Order No. 9,<sup>1</sup> Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the “Saint Thomas Entities”) file this response to the *Plaintiffs’ Steering Committee’s Memorandum in Support of its Proposal for Initial Trial Setting and Pretrial Deadlines for the St. Thomas-Related Defendants* (Docket #1866) (“PSC Proposal”) and *Cross-Motion to Amend MDL Order No. 9* (Docket #1867) (“Cross-Motion”)<sup>2</sup> to show the Court as follows:

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<sup>1</sup> MDL Order No. 9, entered September 18, 2014 (Docket #1425) (“MDL Order 9”).

<sup>2</sup> The Saint Thomas Entities take no position on the PSC’s Cross-Motion to amend MDL Order 9 to the extent it addresses pretrial and discovery matters as to the Premier-related and Box Hill-related Defendants. However, they do take issue with the PSC’s memorandum in support (Docket #1868), which includes a bellwether proposal for the Tennessee cases in the MDL that is not addressed in the Cross-Motion. That memo references and attaches a proposed MDL Order No. 9B—that the PSC later amended further and submitted as an exhibit to the PSC’s opposition to the Saint Thomas Entities’ motion to extend common issue fact discovery (Docket #1900-1). The PSC has made clear that Docket #1900-1 is their live proposal for all purposes, and the Saint Thomas Entities object to that proposal, as explained further in this Response.

## PRELIMINARY STATEMENT

The Saint Thomas Entities have at all times from their first participation in the MDL put forth a balanced and reasonable plan for bellwether selections that takes into account the important interests of obtaining critical information needed to move these cases forward to ultimate resolution and avoid “the risk [of] trying an anomalous case, thereby wasting substantial amounts of both time and money.”<sup>3</sup> The Saint Thomas Entities’ most recent proposal<sup>4</sup> is patterned on the comments from the Court and other parties, as well as the work and scholarship of Judge Fallon and other MDL judges facing similar circumstances who have thoroughly vetted and considered these matters.

By contrast, the PSC’s position lacks any support in the leading MDL authorities and cases. Notably, although the PSC’s position on bellwether trials continues to evolve, its only goal is to get a trial setting as soon as possible on a case of its choosing, giving no consideration to litigation variables or other indicia of representativeness. The PSC now appears to have retreated from its unprecedented proposal of setting six, unilaterally selected cases for a single trial this year and has gone back to the bellwether process that the Court and parties have been crafting since the Saint Thomas Entities were first brought into the MDL. Without citing a single authority, the PSC launches yet another unworkable and one-sided proposal. The Court should reject the PSC’s Proposal and adopt instead that of the Saint Thomas Entities.

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<sup>3</sup> Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2344 (June 2008) [hereafter *Bellwether Trials*].

<sup>4</sup> See *Saint Thomas Entities’ Proposal for Bellwether Trials* (Docket #2419) (“STE Bellwether Proposal”), which is incorporated by reference for all purposes.

## ARGUMENT AND AUTHORITIES

### I. The PSC Has Grossly Mischaracterized the Record

Plaintiffs have brought suit against the Saint Thomas Entities in an attempt to prove their vicarious liability for the administration of contaminated methylprednisolone acetate (“MPA”) by Saint Thomas Outpatient Neurosurgical Center (“STOPNC”), an ambulatory surgery center located in a medical office building on the Saint Thomas West Hospital campus. It is uncontested that neither the Saint Thomas Entities nor STOPNC had *any role whatsoever* in causing the contamination. Nor is there a shred of proof that the Saint Thomas Entities or STOPNC had any knowledge of any contamination by NECC. It is the Saint Thomas Entities’ position that those responsible for the contamination itself are the only parties liable for the injuries caused by this unprecedented outbreak. But now that the PSC has settled with the responsible parties, they have lost all interest in NECC, the Affiliated Defendants, and the National Defendants,<sup>5</sup> instead projecting all the blame on the Saint Thomas Entities, the Tennessee Clinic Defendants,<sup>6</sup> and other

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<sup>5</sup> National Defendants” are the Unaffiliated Defendants who had service agreements or arrangements with NECC or the Affiliated Defendants, but who did not purchase compounded product from NECC.

<sup>6</sup> The Tennessee Clinic Defendants are STOPNC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD PC; and Donald E. Jones MD. Only a subset of the Tennessee Clinic Defendants—those based in Nashville—are defendants in the cases pending against the Saint Thomas Entities. Saint Thomas Network is a 50% investor in STOPNC, and none of the Saint Thomas Entities has any other corporate relationship with any of the other entities. Thus, the PSC’s proffered definition of the “Saint Thomas Defendants” as including both the Saint Thomas Entities and the Nashville Tennessee Clinic Defendants, *e.g.*, Docket #1900-1 at 2 n.7, is at best a transparent attempt to avoid its burden of proving that the Saint Thomas Entities had an agency relationship with the Nashville Tennessee Clinic Defendants, and at worst an attempt to deliberately confuse the issue. The Saint Thomas Entities object to the PSC’s effort to lump all of these defendants together in a misleading global definition or to describe them as “affiliated” when there is no proof that they are.

Healthcare Defendants.<sup>7</sup> And as evidenced by the PSC’s conduct in recent depositions—such as yesterday’s deposition of the CEO of Victory Heating & Air Conditioning Co., Inc. (which designed the HVAC for NECC’s cleanrooms) and the recent deposition of a former key employee of Liberty Industries, Inc. (which designed and installed NECC’s cleanrooms)—the PSC has quickly done a complete about-face regarding the culpability of the settling parties.

The PSC’s Proposal and Cross-Motion incorrectly characterizes the events leading up to the bellwether decisions presently before the Court. For example, the PSC repeatedly criticizes the Saint Thomas Entities as seeking to delay these proceedings, but there is no basis for ascribing any blame for the time lapse to these defendants. The PSC goes so far as to accuse these defendants as having “refused to participate in discovery.” PSC Proposal at 6. That is patently untrue. The Saint Thomas Entities have been diligent in both propounding and responding to discovery. At the same time, they have had to fight an uphill battle to obtain this discovery, much of which was prohibited for a long time under the case-management orders that the PSC sought and obtained before the Saint Thomas Entities—and most of the other Healthcare Defendants—were even in the MDL.

The Court ruled on threshold issues in the Tennessee Defendants’ motions to dismiss on August 29, 2014 (Docket #1360),<sup>8</sup> and MDL Order 9—setting out the timetable, sequencing, and

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<sup>7</sup> “Healthcare Defendants” are the clinics/hospitals and their employees, physicians, nurses, and staff, that injected their patients with NECC-manufactured MPA, and the organizations and individuals alleged to be liable to the Plaintiffs based upon their alleged relationship to the injecting individuals and entities.

<sup>8</sup> It is not entirely clear why the PSC claims a victory in the resolution of the Saint Thomas Entities’ and Tennessee Clinic Defendants’ respective motions to dismiss. *See* PSC Proposal at 6-7. In fact, the Saint Thomas Entities were largely successful in that the ruling eliminated a principal vicarious liability theory against them—alter ego—on the pleadings and narrowed the agency and primary liability theories alleged by the Tennessee Plaintiffs.

procedure governing common discovery—was not entered until September 18, 2014. Moreover, although Judge Boal ordered the form and scope of Plaintiffs’ Profile Forms (“PFF”) and records-release authorizations on February 14, 2014, many of those PFFs and authorizations were not received by the Saint Thomas Entities until close to the November 17, 2014, deadline the Court imposed. Even after the PFFs and authorizations were received in mid-November 2014, the Saint Thomas Entities had to follow up on incomplete PFFs and responded to motion practice initiated by the PSC as to the scope of certain releases, which was resolved on February 24, 2015. *See* Docket #1509. The documents produced by the mediating parties have slowly trickled out, with documents from some parties having been finally produced for the first time in May 2015. In fact, the Saint Thomas Entities learned for the first time last Friday that over 4,000 pages of documents were missing from settling defendant ARL Bio Pharma, Inc.’s production; these documents had never been provided to US Legal for uploading to the repository. And, of course, no depositions have been taken of the individual Plaintiffs or their treaters, much less has any expert discovery occurred, because that part of the litigation has been stayed during the pendency of common fact discovery.

The Saint Thomas Entities are also encountering enormous difficulties obtaining the documents and information they need to show who is actually responsible for this tragedy in order to defend themselves against charges that they are also somehow culpable. Now that the PSC is abandoning its claims against NECC and the Affiliated and National Defendants, the burden of discovering what truly happened at NECC falls to the Healthcare Defendants. And even though the Court carefully carved out precisely this discovery from its *Order Limiting Discovery and Staying These Proceedings with Respect to NECC Insiders and Related Settling Parties* (Docket ##1481, 1482), most of the settling defendants are resisting the Healthcare Defendants’ efforts.

*See, e.g., Saint Thomas Entities' Memorandum of Law in Support of Their Motion for Continuance of Common Issue Fact Discovery Deadline* (Docket #1850).

Considering the circumstances, it is remarkable for the PSC to assert that “the individual discovery needed for defendants to prepare a case for trial has already largely been completed, and the parties have already gone through the process of selecting potential trial pool case picks earlier this year, in the context of the PSC’s motion for expedited trial.” PSC Proposal at 11-12. The PSC is well aware that MDL Order 9 has *stayed* individual discovery on Case-Specific Issues. MDL Order 9 at 3 n.5.<sup>9</sup> Meanwhile, the PSC has had unfettered access to key documents and information from their own clients and the settling defendants. And the suggestion that the Saint Thomas Entities have “select[ed]” their potential trial pool seriously misstates the facts. Rather, the Saint Thomas Entities have at all times pressed the importance of a fair and bilateral process that includes identifying the key litigation variables by the Court and parties before any binding selections are made.

## **II. The PSC’s Proposal Is Unworkable in Concept and as to Timing**

### **A. The PSC’s Proposal Amounts to its Own Opinion That These Cases Should Be Expedited to Trial**

The PSC offers no authority for its proposal—only its subjective view that eight cases are enough for the initial pool, only injury cases should be included, and no strikes are necessary. It never attempts to identify the litigation variables that are critical to determining representative cases from a pool of over 100 plaintiffs. Instead, the PSC wants the parties to pick their best cases

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<sup>9</sup> The PSC’s reference to the HIPAA pre-suit release is misleading in that such a release only pertains to those health care providers to whom the plaintiff chose to send a notice. As detailed above and in the briefs incorporated by reference, the Saint Thomas Entities have only just begun receiving records as to the individual plaintiffs. And there are large gaps in the other discovery and information they have sought from the settling defendants and third parties that will be necessary to defend themselves at trial.

and tee up the first two for trial. The PSC's primary justification for discarding the careful selection process outlined by Judge Fallon and the Saint Thomas Entities is that such a proposal is "needlessly cumbersome and slow[.]" PSC Proposal at 10. Notably, the PSC does not even try to defend its proposal as designed to select representative plaintiffs—only that its plan will move two cases to quick trials.

The PSC also asserts that the issues in this case are especially time sensitive, but that can be said in any MDL involving serious injuries and deaths. PSC Proposal at 7. That was certainly also the case in the Vioxx MDL, where Judge Fallon likewise took seriously the need to move the cases along expeditiously, but also observed that justice is best served by spending the time necessary to select truly representative bellwether cases. The objective of an MDL—as opposed to a single-plaintiff case—is not to get one or more cases to trial as quickly as possible. Instead, the principal goal is to identify and work up representative cases for initial trials:

Bellwether trials thus assist in the maturation of any given dispute by providing an opportunity for coordinating counsel to organize the products of pretrial common discovery, evaluate the strengths and weaknesses of their arguments and evidence, and understand the risks and costs associated with the litigation. Indeed, the utilization of bellwether jury trials can enhance and accelerate the MDL process in two key respects. First, bellwether trials allow coordinating counsel to hone their presentation for subsequent trials and can lead to the development of "trial packages" for use by local counsel upon the dissolution of MDLs. Second, and perhaps more importantly, bellwether trials can precipitate and inform settlement negotiations by indicating future trends, that is, by providing guidance on how similar claims may fare before subsequent juries.

Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2338. The PSC's Proposal honors none of these objectives.

The PSC further seeks unfair advantage in attempting to define the eligible cases to be those with "fungal meningitis or other fungal infections." PSC Proposal at 8 n.25, 11. Conspicuously absent from its proposal are the "fear" or no disease cases that represent 24% of

the Plaintiff population in the cases against the Saint Thomas Entities and Nashville Clinic Defendants. A truly balanced proposal would take into account representative cases from all health outcomes. *See, e.g.*, STE Bellwether Proposal at 7-9. The PSC's proposal is anything but balanced.

Finally, the PSC's proposal lacks a number of important considerations and safeguards that the Saint Thomas Entities have previously indicated are necessary, yet fails to offer any legitimate explanation as to why they are not. For example, the size of its initial pool of eight is too small to cover even the five categories of injury, yet the PSC says only that 16-20 is too large. *Compare* PSC Proposal at 10 (“[C]hoosing eight cases creates a more manageable Pool . . .”) *with* Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2347 (“If the pool is too small, then there is a risk that too few of the major variables will be properly represented.”). As to the Saint Thomas Entities' position that some limited discovery will be needed as to the agency issues before binding selections are made, the PSC says only that it should be avoided. PSC Proposal at 10. And as noted, there is no attempt to identify or quantify any litigation variables. Nor is there any mechanism for the parties to strike outlier cases. The PSC's dismissal of these important considerations speaks volumes.

#### **B. The Deadlines in the PSC's Proposal Are Simply Not Possible**

The Saint Thomas Entities have previously briefed the issues inherent in the PSC's attempt to rush justice, *see* Docket ##1753, #1870, and will not restate them here. Those briefs did not have the benefit of the PSC's newest proposal for *[Amended Proposed] MDL Order 9B: Order Regarding Common Issue Discovery* (Docket #1900-1) (“Proposed Order 9B”).

The PSC's Proposed Order 9B timetable for the Tennessee cases is entirely unrealistic and creates undue pressure on the Court and the parties. To give but a few examples, the proposal

would require the parties to file submissions requesting the Court to set the order of the eight Pool cases, and the Court is expected to rule within the two weeks following. *Id.* at 4. The parties then have three weeks to disclose experts—and must do so simultaneously<sup>10</sup>—with rebuttal expert reports coming three weeks later and no opportunity for deposition first. *Id.* All expert depositions are expected to be completed in a mere 35 days, which includes the Thanksgiving holidays, and all of this is to happen within two months of selecting the first trials. *Id.*

*Daubert* motions and Case-Specific dispositive motions are proposed to be due merely six days after the depositions are completed. Even if the parties were not already experiencing delays in obtaining deposition transcripts, this deadline would be wholly impractical, particularly in the event that there are multiple dispositive motions addressing distinct issues among the various cases. And there is no time for the Court to actually consider the dispositive motions, which are squeezed into the tight timetable, in the 17 days between receipt of the reply briefs and the date by which the cases should be “trial-ready.” The PSC’s Proposal should be rejected in its entirety.

## **CONCLUSION AND PRAYER**

For these reasons, the Saint Thomas Entities request that the Court reject the PSC’s Bellwether Proposal and Proposed Order 9B, enter the Saint Thomas Entities’ bellwether proposal, and grant such other and further relief to which the Saint Thomas Entities are entitled.

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<sup>10</sup> Before this proposal, all of the parties had anticipated a more traditional and effective sequencing where the plaintiffs would first designate their experts, and the defendants would designate theirs after a reasonable time and opportunity to depose the experts, similar to the sequencing set forth for common expert discovery in MDL Order 9. The Saint Thomas Entities object to any proposal that does not include such sequencing.

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FORMERLY KNOWN AS ST. THOMAS  
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By their attorneys,

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**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 10th day of June, 2015.

*/s/ Sarah P. Kelly*  
SARAH P. KELLY